PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

HEADQUARTERS
501 FRONT ST.
NORFOLK, VA 23510
757-622-PETA
757-628-0781 (FAX)

July 7, 2004

Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Bldg. (1101A)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Comments on the HPV test plan for 1,2-benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 2-(2-hydroxyethoxy) ethyl 2-hydroxypropyl ester

Dear Administrator Leavitt:

Albemarle Corp. and Great Lakes Chemical Corp. submitted an HPV test plan for 1,2-benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 2-(2-hydroxyethoxy) ethyl 2-hydroxypropyl ester, or tetrabromophthalic anhydride diol (TBPA diol; CAS no. 77098-07-8). These comments on this test plan are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The sponsors are proposing to conduct an oral, repeated-dose toxicity test on TBPA diol, without stating the method to be used. If the test method used is OECD no. 407, this will involve killing at least 40 animals. The sponsors leave open the possibility of also conducting a reproductive toxicity test and/or a developmental toxicity test, depending upon the results of the repeated-dose test. A reproductive and/or developmental test will kill an additional 675 animals, at a minimum, and, depending upon the method(s) selected, could kill up to several thousand (e.g. if OECD nos. 414 and 415 are carried out).

TBPA diol is a brominated flame-retardant. There is currently a great deal of concern about the endocrine-disrupting activities of brominated flame-retardants, and a large research program in this area will probably be launched in the near future by the EPA and equivalent agencies worldwide. The sponsors should have taken this issue into consideration when preparing the test plan. For example, it is possible that concerns about endocrine disruption will necessitate such a marked decrease in the use of brominated flame-retardants that a high production volume program will no longer be relevant. Even if this is not the case, it may be possible to obtain the required data in the course of the endocrine research, in which case a separate HPV testing program will be superfluous. The sponsors should not have submitted the test plan for TBPA diol without a discussion of the wider context.

Another class of brominated flame retardants, the diphenyl ethers, was the subject of a recent review by the EPA's Voluntary Children's Chemical Exposure Program (VCCEP). The VCCEP expert panel concluded that additional animal testing was not warranted for these substances. While the panel did not identify toxicity as a data gap, environmental persistence was a cause for concern. Both Great Lakes and Albermarle submitted an enormous amount of data to the

VCCEP at the time. We would therefore like to know what attempt these sponsors have made to draw upon the vast amount of animal data from another class of brominated flame retardants in order to minimize new testing for TBPA diol.

Furthermore, the sponsors provide little information about human exposure to TBPA diol (test plan, p. 2). Data on exposure should have been included, since, taking into consideration the low acute toxicity of TBPA diol (LD_{50} > 2 g/kg), it is possible that tests will not be needed if the exposure is very low.

In addition to the repeated-dose, and reproductive and developmental toxicity tests, the sponsors propose carrying out an *in vitro* chromosomal aberration test on TBPA diol. The cells used in this study should either human lymphocytes or mammalian cells obtained from established cultures, so as to avoid killing additional animals in order to supply the cells.

I can be reached at 757-622-7382, ext. 8001, or via e-mail at JessicaS@peta.org.

Sincerely,

Jessica Sandler
Federal Agency Liaison